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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/381,484
Filing Date: February 28, 2000
Appellant(s): SCHADE ET AL.

Nichole T. Andrighetti
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 24, 2006 appealing from the Office action mailed June 8, 2005.

(1) **(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

US Patent 5,374,657	Kyle et al.	December 20, 1994
EP 0231904	Albright	August 12, 1987 (with English Translation)

Crozier "Metabolism of long chain polyunsaturated fatty acids and infant nutrition," Monatsschrift Fur Kinderheilkunde, Vol. 143, No. 7(suppl. 2), 1995, pages 95-98

(9) Grounds of Rejection

Claim Rejections 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 14-17 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (U.S. Patent 5,374,657) in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS) and Schweikhardt et al (IDS).

Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk, (which are about 26 mg/kcal of ARA and 8 mg/kcal of DHA, see applicants response of 11/17/03). The ratio of ARA:DHA is about 3:1 to 2:1. See the claims and the examples in columns 13-16. Kyle also teaches that the presence of ARA and

DHA in infant food is critical for a healthy growth for infants. See, particularly, column 1, lines 29-53.

Kyle does do teach expressly the administration of the infant formula to preterm infants, or the particular ratio of ARA: DHA, and the particular amounts of ARA: DHA herein.

However, Crozier et al. teaches that the presence of ARA and DHA in food is particularly important for preterm infants to proper growth and development because they are unable to synthesize sufficient ARA and DHA. See, particularly, the summary. Schweikhardt et al. also teach to employ ARA and DHA enriched infant formula for feeding pretermed infant, wherein the ration of ARA and DHA is essentially the same as herein claimed. See, particularly, page 1, the third paragraph and the claims of the English translation. Schweikhardt et al. further teach an oil mixture for infant formula comprising 0.12 –1% of ARA and 0.05 –0.5% of DHA. These amount would translated to about 5-42 mg/kcal of ARA and 1.7 to 17 mg/kcal of DHA in a infant formula (based on 100 ml of infant formula contain 3.5 g of oil mixture and 120 ml of infant formula provide 100 kcal of energy (see table 1 at pages 5-6 of the translation).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding pretermed infant.

A person of ordinary skill in the art would have been motivated to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding pretermed infant, because preterm infants are known to be in need of food with sufficient amount of ARA and DHA and the particular amounts of ARA and DHA herein are overlapped with the amounts range known in the art. The particular amount herein is considered obvious variation within the

known range. Further, optimization of the amounts of ARA and DHA, or the formula as whole, particularly for preterm infants are considered within the skill of artisan since the criticality of ARA and DHA for preterm infant growth is known in the art. Note the claimed ratio of ARA:DHA is within the broad range claimed by Kyle. See, particularly, claim 20 in Kyle.

As to the limitation of "weight gain," note the claims are directed to a formula and the its ultimate utility, i.e., feeding pretermed infant with formula comprising ARA and DHA. Such utility has been fairly suggested by the cited references as discussed above. The intended function of the utility herein fails to distinguish the claimed method from what have been suggested by the prior art. Particularly, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." The ultimate utility for the claimed composition is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

(10) Response to Argument

In response to applicant's argument that the cited references as whole do not teaches the benefit herein claimed, i.e., "weight gain", the fact that applicant has recognized another

advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The claimed inventions are directed to a infant formulation comprising DHA and ARA, and method of using the same for feeding pretermed infant. The cited references teaches the criticality of DHA and ARA for pretermed infant, and teaches the ratio of DHA and ARA herein in the formula. Therefore, to make such infant formula as claimed herein and use the same for feeding pretermed infant would have been obvious to one of ordinary skill in the art. Thus, a prima facie case of obviousness has been established.

Further, in response to appellant's arguments, the recitation "for enhancing the weight gain" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Furthermore, appellants fail to establish an unexpected result sufficient to rebut the prima facie obviousness. "The evidence relied *>upon< should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). See also MPEP 716.02(b). The cited references teach that DHA and ARA are necessary for pretermed infant to proper growth and development. One would have reasonably expected the DHA and ARA would lead to

enhancement of weight gain in pretermed infant. Even if the references do not explicitly teaches DHA and ARA will lead to improvement of weight gain, The cited references, as a whole, still provide sufficient motivation to one of ordinary skill in the art to use DHA and ARA for feed pretermed infant. Therefore, appellant fails to establish that the evidence relied *>upon< establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance."

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Shengjun Wang

SHENGJUN WANG
PRIMARY EXAMINER

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